THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte

TSE W. CHANG

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Appeal No. 1995-3148
Application 08/011,130[1]

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 6 and 8 through 14, all the claims pending in the application. Claims 6, 8, 11 and 13 are representative of the subject matter on appeal and read as follows:

[1] Application for patent filed January 28, 1993. According to appellant, this application is a continuation-in-part of Application 07/926,566, filed August 6, 1992, now abandoned, which is a continuation of 07/688,000, filed April 19, 1991, now abandoned.

6. A pharmaceutical composition comprising a pharmaceutical vehicle and a molecular conjugate having a polymer backbone coupled with a plurality of binding molecules which lack an Fc portion and which are specific for an antigen on a T cell.

8. A pharmaceutical composition of claim 6, wherein the polymer is hydrophilic, stable, nonimmunogenic in humans, and resistant to hydrolysis in human body fluids.

11. A mixture of two or more molecular conjugates combined with a pharmaceutical vehicle, each comprising a polymer backbone coupled with a plurality of binding molecules of one class, each class being specific for different monovalent antigenic epitopes on the same antigen on T cells, and all said binding molecules lacking an Fc portion.

13. A pharmaceutical composition comprising a pharmaceutical vehicle and a molecular conjugate having a polymer backbone coupled with a plurality of different binding molecules which each bind noncompetitively to monovalent antigenic epitopes on the same antigen on T cells, and all said binding molecules lacking an Fc portion.

The references relied on by the examiner are:

Goers et al. (Goers) 4,867,973 Sep. 19, 1989

J.M. Williams, et al. (Williams), “The Events of Primary T Cell Activation Can Be Staged by Use of Sepharose-Bound Anti-T3 (64.1) Monoclonal Antibody and Purified Interleukin 1,” Journal of Immunology, Vol. 135, No. 4, (1985), pp. 2249-2255.

T. Geppert, et al. (Geppert), “Accessory Cell Independent Proliferation of Human T4 Cells Stimulated by Immobilized Monoclonal Antibodies to CD3,” Journal of Immunology, Vol. 138, No. 6, (1987), pp. 1660-1666.

Roitt, Immunology, Gower Medical Publishing (1995), page 8.7, figure 8.19.

Claims 6 and 8 through 14 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Williams, Geppert, Goers and Roitt. Claims 6

and 8 through 14 also stand rejected under 35 U.S.C. § 101 as being inoperative, and under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. We reverse the rejection under 35 U.S.C. § 103. We do not reach the merits of the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, and remand this application to the examiner for reevaluation of those rejections in light of U.S. Patent No. 5,872,222.

35 U.S.C.§ 103

All of the claims on appeal are directed to pharmaceutical compositions comprising a molecular conjugate having a polymer backbone coupled with a plurality of binding molecules specific for a T-cell antigen. Individual claims require that the polymer is nonimmunogenic in humans; that the polymer is resistant to hydrolysis in human body fluids; that the composition comprises a mixture of two or more conjugates, each specific for a different T-cell epitope; etc. All of the claims, however, require that the binding molecules lack Fc portions.

Williams and Geppert each discloses activation of T-cells with anti-CD3 antibodies bound to Sepharose, but neither discloses T-cell binding molecules lacking Fc portions. Nor does the examiner rely on Goers or Roitt to remedy this deficiency. The statement of the rejection contains only an oblique reference to binding molecules

that lack Fc portions: “Fv, Fab and F(ab’)2 fragments of antibodies and methods of producing these fragments are well known in the art.” See the Answer, page 6.

Appellant argues that the references teach nothing more than conjugates comprising polymers coupled to intact anti-CD3 antibodies. In responding to these arguments, the examiner does not dispute this. Instead, for a number of reasons set forth on pages 17 through 19 of the Answer, the examiner maintains that “a person of ordinary skill in the art would realize that the Fc region is only required when non-bound antibodies are used in the in vivo system” and that person would also “have known that any argument regarding Fc is a non-issue, and is textbook knowledge.” (Examiner's Answer, page 18).

Our determination of the patentability of the claims is hampered by the examiner’s failure to specifically acknowledge or address this limitation in the statement of the rejection. We have no doubt that the prior art could be modified in a manner consistent with appellant’s specification and claims. That the prior art could be so modified, however, would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). What is lacking from the examiner’s treatment of the claims on appeal is a reason, suggestion or motivation, stemming from the prior art,

which would have led a person having ordinary skill to the claimed method. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). In our judgment, the only reason or suggestion to modify the references to arrive at the present invention comes from appellant's specification. Accordingly, the rejection of claims 6 and 8 through 14 under 35 U.S.C. § 103 is reversed.

35 U.S.C. §§ 101 and 112

U.S. Patent No. 5,872,222 (the '222 patent) issued from application serial no. 07/993,291, an application closely related to the present application. Claims 1 and 7 of the '222 patent read as follows:

> 1. A conjugate comprising a substantially nonimmunogenic polymer coupled with a plurality of binding molecules, each being specific for an antigen on a T cell, and said binding molecules lacking an Fc portion.
>
> 7. An improved method for producing antibodies against an immunogen, comprising administering the conjugate of claim 1 to a host animal together with the immunogen and thereby increasing the immunogenic response against the antigen, and screening for antibodies, or cells producing antibodies, which are specifically reactive with the immunogen.

The patented conjugate (claim 1 of '222) is closely related to and parallels the pharmaceutical conjugates that are the subject of this appeal, inasmuch as the patented conjugate is administered to a host animal together with an immunogen to increase the host's response to the immunogen (claim 7 of '222).

Thus it appears that the continued rejection of the claims in the present application under 35 U.S.C. §§ 101 and 112, first paragraph, is inconsistent with the determination that claims 1 and 7 of '222 are patentable. Accordingly, we remand the application to the jurisdiction of the Examining Corps to allow the examiner to consider the '222 patent and determine its effect, if any, on the issues raised in this appeal under 35 U.S.C. §§ 101 and 112, first paragraph.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REVERSED AND REMANDED

SHERMAN D. WINTERS Administrative Patent Judge	)	
WILLIAM F. SMITH Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
HUBERT C. LORIN Administrative Patent Judge	)	

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